

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Shirai, et al.
App. No	:	10/521,958
Filed	:	January 21, 2005
For	:	INDOMETHACIN EXTERNAL PREPARATION
Examiner	:	Jean-Louis, Samira
Art Unit	:	1617
Conf #	:	2101

PETITION FOR SUSPENSION OF ACTION UNDER 37 C.F.R. § 1.103(a)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is a request for suspension of action for three months under 37 C.F.R. § 1.103(a) for good and sufficient reason.

The suspension is requested to provide three months for generation of data to rebut the rejections of the present claims as obvious over Kimura (JP 10-182458) or Inagi (US 4309414).

As discussed in the personal interview of June 30, 2008 with Examiner Samira Jean-Louis and her Supervisor, Sreeni Padmanabhan, the inventors have solved the problem of phase separation in gel-cream formulations by inclusion of a "component selected from the group consisting of glyceryl monostearate, sorbitan monostearate, stearyl alcohol, and polyethylene glycol monostearate" having "a melting point of 40°C or higher" (see present claim 1). Inclusion of a component selected from the above list prevents phase separation which occurs in gel-cream formulations which have relatively high concentrations of both an alcohol and an oil component.

A Declaration under 37 C.F.R. § 1.132 was submitted with the response of January 16, 2008 which included a comparison of polyethylene glycol monostearate (40EO) which has a melting temperature of 42-47°C with polyethylene glycol monostearate (4EO) having a melting

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point of less than 40°C (that is, 31-36°C). The data demonstrated that the formulation containing 40EO according to the claimed invention was stable at 2 months, while the formulation outside of the claimed invention (4EO) showed phase separation at two months (see Tables 2 and 3 of the Declaration).

At the interview, the Examiner's supervisor agreed that the data presented in the Declaration supported a showing of unexpected results for a formulation encompassing 40EO. Applicants respectfully request a three month suspension of action to obtain similar data for additional surfactants falling within the scope of the claims. In order to demonstrate the improved stability achieved by additional formulations within the scope of the claimed invention, a period of time is needed to conduct experiments comparing the additional formulations to similar preparations having a melting point outside the scope of the claims (less than 40°C). Applicants will then present the evidence in the form of a second Declaration under 37 C.F.R. § 1.132 to further address the outstanding obviousness rejections over Kimura (JP 10-182458) and Inagi (US 4309414) as discussed at the June 30th interview.

This petition is accompanied by the petition fee of \$200 as set forth in 37 C.F.R. § 1.17(g).

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: Sept. 8, 2008

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